UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO ALL CLASS ACTIONS	

PLAINTIFFS' SUPPLEMENTAL FACTUAL AUTHORITIES BASED ON NEW EVIDENCE SUBMITTED IN SUPPORT OF PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

[REDACTED VERSION]

Plaintiffs seek to briefly supplement the record on class certification based upon information from defendants' own documents, gathered or analyzed after the class certification hearing, to briefly address three points germane to class certification. One, defendants' own documents evidence that plaintiffs can prove the use of AWP as a reimbursement benchmark in the oral drug marketplace and can do so without all of the complicating factors defendants assert are part of pharmaceutical pricing in the retail market. Second, contrary to defendants' argument and that of their hired expert, Mr. Young, defendants' own documents and marketing tools reveal that physicians administering drugs to patients are reimbursed based on AWP both by Medicare and by insurers outside the Medicare system. Third, recent discovery reveals that Gregory Bell, defendants' lead tutorial expert, was actually a retained consultant who advised BMS on how to teach the BMS sales force on how to exploit the AWP spread. Recognizing the illegality of such conduct Bell even advised BMS to make sure "no printed materials" were created in making such sales pitches to physicians. Surely, such participation in the scheme that this litigation is based on is relevant to the weight given by the Court to his testimony, as well as defendants' argument based on such testimony.

A. The Use of AWP as a Benchmark for All Drugs

One component in the proof common to the oral drug class is the near universal use of AWP as a reimbursement benchmark. To defeat plaintiffs' showing of commonality, defendants claim that there is "complexity and variability" in pricing.[1] The following recently-discovered materials add support to the fact this element of proof can be established on a class-wide basis without individualized proof as defendants suggest.

[1] *See, e.g.*, Defendants' Tutorial Script at 46.

Defendants studied the reimbursement of drugs at the macro level in the retail market and have uniformly concluded that AWP is the basis for reimbursement. For example, a 2004 Pharmacy Benefit Report, prepared by Novartis, reports the use of AWP as a reimbursement benchmark for all [redacted], including commercial payors such as HMOs and PPO groups.[2] For brand-name drugs, the Novartis report notes that managed care organizations [redacted]. Again, this establishes defendants' knowledge concerning both uniformity of the use of AWP and reflects market-wide absence of the knowledge of spreads vastly exceeding this range. It tracks precisely with Dr. Hartman's yardsticks based upon market expectation of a difference between AWP and acquisition cost of 15%.

A BMS document entitled [redacted] also admits that AWP is the class-wide basis for reimbursement:

[redacted][3]

AstraZeneca in a pricing strategy memorandum noted:

[redacted][4]

[2] *See* Appendix A.1. All attachments are submitted herewith in Plaintiffs' Appendices A-C in Support of Plaintiffs' Supplemental Factual Authorities Based On New Evidence Submitted in Support of Plaintiffs' Motion for Class Certification.

[3] Appendix A.2 at BMS/AWP/00480643-44.

[4] Appendix A.3 at AZ0463895.

The AstraZeneca strategy memorandum goes on to note that the pharmacists are also interested in AWP since it is the [redacted][5]

In a document entitled [redacted] the author who was retained in multiple instances to provide training to AstraZeneca employees illustrated exactly how and why AWP is the foundation for reimbursement:[6]

[redacted]

[redacted]

[5] Appendix A.3 at AZ0463895.

[6] Appendix A.5 at A20602198-99.

A Schering-produced document illustrates how brand-name and generic drugs are formulaically linked to AWP and calculates how much "margin" a pharmacist makes off the spread on Proventil,[7] as well as how managed care companies pay based upon AWP minus a discount of 13% on brand-name drugs and 40% on generics.[8] With respect to its top-selling drug Claritin, Schering implementing a marketing strategy to overcome an [redacted][9]

Again, such evidence supports plaintiffs' contention that proof of AWP as a standard benchmark is not only possible for this litigation, but is exactly what defendants knew and relied on for their marketing efforts.

Defendants' tutorial expert Mr. Bell was part of the BMS' Tequin pricing team. That team recommended that Tequin be priced based upon [redacted] Nowhere in the strategy materials[11] does Bell or BMS make any reference to AWP being so individualized in its use in the market that it could not be the basis for a pricing strategy.[12] Indeed, rather than the myriad of complicating factors, Mr. Bell's presentation to his team demonstrates that he believed that the pricing of brand name drugs was rather simple:

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[7] Appendix A.4 at SP0012555.

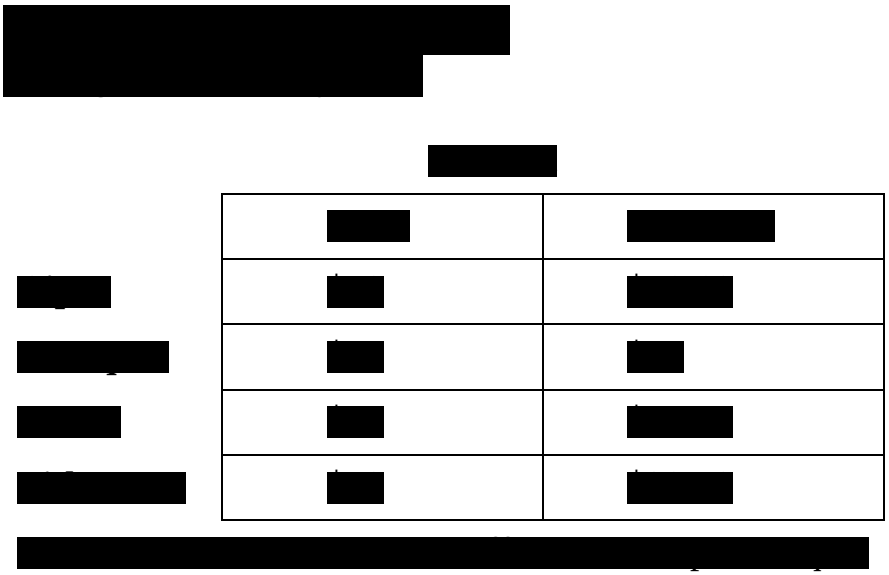
[8] Appendix A.4 at SP0012556.

[9] Appendix A.6 at SW0648213.

[10] Appendix C.3 at BMS/AWP/01278484.

[11] Appendix C.3 at BMS/AWP/01278456.

[12] *See also* Appendix C.3 at BMS/AWP/01278475 (discussing AWP based pricing of five BMS drugs).



And he recommended pricing based on AWP in order to win in the retail market.[13]

B. The Use of AWP as a Basis for Reimbursement for Physician-Administered Drugs

The second area of supplementation concerns the use of AWP as a reimbursement benchmark for physicians administering drugs not covered by Part B. Defendants disputed that AWP is the basis for reimbursement in such circumstances.[14] In particular Young has put before the Court his purported review of the evidence on this issue. It has become apparent that his opinions are rebutted by defendants' own documents.

Defendants studied how the physician-administered market operated on a macro level and concluded that physicians were paid based upon AWP. For example, a BMS memorandum analyzes reimbursement in the oncology market and notes that drug reimbursement is a

[13] *Id*. at BMS/AWP/01278505.

[14] *See* Defendants' Tutorial Script at 50.

[redacted][15] [Emphasis added.]

This evidence is contrary to defendants' and Mr. Young's assertions, for the purposes of this litigation, that physicians are not reimbursed based upon AWP.[16] Further the widespread use of a predetermined formula using AWP is supportive of plaintiffs' motion for class certification.

On a drug-by-drug level, defendants often prepared marketing documents that compared how their drug made physicians more money based on the spread. These marketing documents make it clear that doctors administering drugs to patients who are Medicare Part B patients or covered by insurance are paid based on AWP in either instance. For example, a Johnson & Johnson document shows the use of AWP by doctors prescribing Procrit to both Medicare and Private Payor Patients.[17]

Appendix B.1 (MDL-CEN00003485) is a worksheet passed out by defendant Johnson & Johnson which allows doctors to calculate how much profit they will make using AWP. The worksheet plugs in AWP. If AWP was not the basis for physician reimbursement, there would be no need for such a worksheet.

Appendix B.2 is an analysis undertaken by a consultant hired by AstraZeneca to survey the pricing of Zoladex. The consultant concluded that after completing an overview of

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[15] Appendix B.9 at BMS/AWP/00393437.

[16] The American Society of Clinical Oncology, in a letter to CMS Administrator Thomas Scully, also refutes defendants' claims about the reimbursement market. The Society, comprised of doctors who administer drugs, wrote that "AWP is used as a benchmark for reimbursement by virtually all public and private insurance programs, both for drugs ***administered in physicians' offices*** and for drugs obtained at retail pharmacies. This letter, coming from the physicians' trade association, completely refutes the assertions of both Young and Bell on this topic. *See* http://www.asco.org/asco/downloads/101003_Alert_-_ASCO_Comments.pdf.

[17] Appendix B.10 at MDL-0BI00055451.

[redacted] the authors concluded that [redacted] *Id*. at AZ 0021720.

Appendix B.3 is the [redacted]. It is a document provided to guide doctors on coverage and reimbursement issues. In direct constraint to Mr. Young's assertions, the Zoladex guide states: [redacted] *Id*. at PXL02772. With respect to private insurance carriers (*i.e.*, class members), the guide advises doctors that they can charge based on AWP.[18]

Appendix B.4 is another AstraZeneca guide to [redacted] this time for Zoladex and Casodex. It notes that in the private payor area, [redacted] *Id*. at AZ0427879. It also identifies the specific J-code for both drugs, again refuting Young's assertions on the ability to track payments based on AWP. *Id*. at AZ0692057.

In a memorandum proposing price increases for the physician-administered drug Kytril, SmithKline (now part of GSK) observes that such an increase will [redacted][19] This document makes no mention that such profit potential is limited to Medicare Part B patients. In price comparisons materials used to promote Kytril and Zofran, Kytril is promoted by GSK as superior in that it provides [redacted][20] Again, this spread is not limited to Medicare patients. GSK's [redacted] concludes that in physician offices, [redacted]

[18] Appendix B.3 at PXL02780.

[19] Appendix B.5 at GSK-MDL-KY01 007599.

[20] Appendix B.6 at GSK-MDL-KY01 004553.

[redacted] And GSK's reimbursement spread analysis for private payors uses AWP as the basis for calculating the spread.[21] There would be no benefit in showing doctors this spread advantage if they were not being reimbursed based on AWP.

C. Defendants' Tutorial Expert Gregory Bell Was Part of BMS' Efforts to Market the Spread

As they did with Professor Berndt, defendants hid from the Court their tutorial expert's deep ties to the industry. In this case, so deep, that their tutorial expert Mr. Bell was involved in counseling BMS to implement the type of unlawful spread marketing conduct at issue here. Mr. Bell's firm Charles River Associates was hired by BMS to develop a marketing strategy. Bell was the [redacted][22] Appendix C.2 is a presentation given by Bell and Charles River Associates to BMS on the marketing of the drug paraplatin. Mr. Bell begins by noting that deconversion [redacted][23] Throughout the PowerPoint, Bell emphasizes the use of marketing the spread as a tactic to convert doctors to BMS' paraplatin:

[redacted]

- [redacted][24]

Elsewhere in advising BMS how to set prices, Bell Advises BMS to take advantage of: [redacted][25] Apparently, aware of the questionable legality of this

[21] Appendix B.7 at GSK-MDL-ZN02-103561. *See also* Kytril pricing plan noting the use of AWP in Medicare, Medicaid and private payor situations. Appendix B.8 at GSK-MDL-ZN02-052895.

[22] Appendix C.1 at BMS/AWP/01253086.

[23] Appendix C.2 at BMS/AWP/01233114.

[24] *Id*. at BMS/AWP/01233118.

conduct, Bell then advises BMS not to create a written record of the sales forces' marketing of the spread: [redacted][26] Bell also advises that physicians be educated on [redacted] in other words, of the margins that could be made on the spread.[27]

Nowhere in these materials does Bell claim that oncologists' reimbursements are so diverse or complicated that no uniform approach is possible. That is of course what he informed the Court in his tutorial. But more importantly, Bell as a paid consultant to BMS was actively involved in advising BMS on how to play the AWP spread game that is at the heart of this lawsuit. Both Bell and BMS were aware of Bell's participation and failed to disclose his involvement to the Court. The testimony of a participant in the wrongful conduct at issue should not be considered by the Court as "expert testimony," or at best it should be heavily discounted.

DATED: July 21, 2005

By **/s/ Thomas M. Sobol**

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[25] *Id*. at BMS/AWP/01233120.

[26] *Id.* at BMS/AWP/01233134.

[27] *Id*. at BMS/AWP/01233154.

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CERTIFICATE OF SERVICE

I hereby certify that I, Thomas M. Sobol, an attorney, caused a true and correct copy of the foregoing, **PLAINTIFFS' SUPPLEMENTAL FACTUAL AUTHORITIES BASED ON NEW EVIDENCE SUBMITTED IN SUPPORT OF PLAINTIFFS' MOTION FOR CLASS CERTIFICATION** to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on July 21, 2005, a copy to Verilaw Technologies for Posting and notification to all parties

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